

510(k) Summary

Prepared:

August 8, 2002

*K023750***Submitter:**

Company Name: Canon USA, Inc. (U.S. agent/official correspondent for Canon Inc.)
 Company Address: One Canon Plaza
 Lake Success, NY 11042
 Contact Person: Ms. Sheila Driscoll
 Phone Number: (516) 328-5602
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Proposed Device:

Reason For 510(k): New Model
 Manufacturer: Canon Inc.
 Trade Name: Canon
 Model Name: CXDI-40G
 Classification Name: MQB, Solid State X-ray Imager
 FDA 510(k) #: To be assigned

Predicate Device:

Manufacturer: Canon Inc.
 Trade Name: Canon
 Model Name: CXDI-11/CXDI-22
 Classification Name: 90MQB, Solid State X-ray Imager
 FDA 510(k) #: K981556/K992547

Description Of Device:

The Canon digital radiography CXDI-40G is used to directly capture and convert conventional projection X-ray images to digital images. A sub-sampled image can be displayed on a preview monitor for viewing. The diagnostic image can be transmitted through a DICOM compatible digital network for printing. The device provides digital image capture for conventional film/screen radiographic examinations. The Canon digital radiography CXDI-40G is different from CXDI-11 and CXDI-22 in the following respect:

- The CXDI-40G operates in conjunction with an upright stand, table, and universal stand while the CXDI-11 operates only in conjunction with an upright stand, and the CXDI-22 only operates in conjunction with a table.

Intended Use:

Canon digital radiography CXDI-40G provides digital image capture for conventional film/screen radiographic examinations. The device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures.

Technical Characteristics:

Please refer to the attached COMPARISON CHART.(Table 10)

Descriptive Comparison

The predicate device is the Canon digital radiography CXDI-11 cleared under Document Number K981556 on November 4, 1998 and CXDI-22 cleared under Document Number K992547 on October 13, 1999.

The CXDI-40G's technical specifications (including image size, pixel pitch, number of pixels), imaging principle, physical characteristics and intended use are the same as those of CXDI-11 and CXDI-22. However, the differences in the design are as follows:

- The mechanical structure and physical appearance of the CXDI-40G are different than the CXDI-11 and CXDI-22. Please refer to the attached CXDI-40G comparison table provided in this section. Additional information can also be found in the CXDI-40G Operation Manual provided in this submission.
- The CXDI-40G can be used with upright stand, table, and universal stand by using the installation unit for each application, while the CXDI-11 is used with upright stand only and the CXDI-22 is only used with a table.
- A removable, fixed grid is used for the CXDI-40G, while an implemented, moving grid is used for the CXDI-11 and a removable moving grid is used for the CXDI-22. Both types of grids are used for eliminating the dispersed X-ray in exposures that use films.
(See attached Table 4.2)

Regarding the software:

- The system software for controlling CXDI-40G is released as V5.0.
- V5.0 includes some changes from V4.1.
- The main changes of the V5.0 are the addition of the control of CXDI-40G sensor and some change of GUI.
- V4.1 was first introduced and cleared under K003689 and is currently used in Canon models CXDI-11, CXDI-22, and CXDI-31.
- The comparison between V5.0 and V4.1 is described in the Software Information for model CXDI-40G section.

Based on the information in this submission, similarity to the predicate devices (Canon digital radiography CXDI-11 and CXDI-22), and the results of our design control activities, it is our opinion that the Canon digital radiography CXDI-40G described in this submission is substantially equivalent to the predicate devices

Table 10 Table of comparison

Item		CXDI-11	CXDI-22	CXDI-40G
FDA 510(k)#		K981556	K992547	Proposed Device
Intended Use		Provide diagnostic images for general radiography with upright system	Provide diagnostic images for general radiography with table system	Provide diagnostic images for general radiography
Design		Digital acquisition, electronic processing	Same	Same
Energy Uses		Receives x-radiation generated by external diagnostic x-ray generator	Same	Same
Materials	X-ray Absorber	Fluorescent screen ($\text{Gd}_2\text{O}_2\text{S}:\text{TB}^{3+}$)	Same	Same
		Visible emission peak: 545nm		

Item		CXDI-11	CXDI-22	CXDI-40G
Sensing Means		Amorphous Silicon W/TFT Array	Same	Amorphous Silicon W/TFT Array
		Detection peak: 540- 620nm		Detection peak: 540- 620nm
Anatomical Sites		General radiography	Same	Same
Target Population		General population	Same	Same
Physical Safety		Minimize exposure to x-radiation	Same	Same
Compliance with Standard		Complies with IEC 601-1-2	Same	Same
Biocompatibility		N/A	N/A	N/A
Performance		After digital processing (optimize the gray-scale)	Same	Same
Labeling		Approved 510(K)	Approved 510(K)	Approved 510(K)
Pixel		2688 × 2688 pixels	Same	Same

Item	CXDI-11	CXDI-22	CXDI-40G
	(7,200,000 pixels)	Same	Same
Image size	43cm × 43cm	Same	Same
Pixel pitch	160 μ m	Same	Same
MTF	MTF@2lp/mm 42%	Same	Same
Dynamic Range	Dynamic range: approximately 4 digit (linear A/D : 14bit) (output data : 12bit)	Same	Same
Grid	Moving grid	Moving grid (removable)	Stationary grid (removable)
Sensor Unit Dimension	552 x 598 x 231mm	604 x 645 x 73.5or69mm	550x 550 x 68mm

Item	CXDI-11	CXDI-22	CXDI-40G
			550x 550 x 116mm (with option parts)
Power Supply Dimension	580 x 489 x 275mm	390 x 160 x 110mm	390 x 160 x 110mm
Control PC Dimension	483.5 x 594 x 300mm	453 x 594 x 300mm	453 x 594 x 300mm
Operation Unit Dimension	298 x 209.5 x 130mm	Same	398 x 395 x 150
Card Reader Dimension	50 x 180 x 39mm	Same	Same
Stand Dimension	900 x 475 x 2100mm	N/A	(900 x 480 x 2000) *
Table Dimension	N/A	(2025 x 820 x 890) *	(2025 x 820 x 890) *

*: These dimensions are applicable for the stand and the table made by canon inc. It is possible to use another stands and tables.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 22 2002

Canon, Inc.
% Ms. Pamela K. Gwynn
Engineering Team Leader
Underwriters Laboratories, Inc.
12 Laboratory Drive
Research Triangle Park, NC 27709

Re: K023750
Trade/Device Name: Canon Digital Radiography
Model CXDI-40G
Regulation Number: 21 CFR 892.1630
Regulation Name: Electrostatic x-ray
imaging system
Regulatory Class: II
Product Code: 90 MQB
Dated: November 7, 2002
Received: November 8, 2002

Dear Ms. Gwynn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

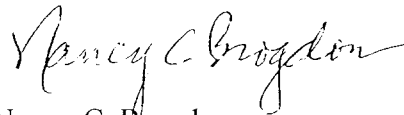
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications Statement

Page 1 of 1

510(K)Number(if known): K023750

Device Name: _____

Indications for Use:

CANON DIGITAL RADIOGRAPHY CXDI-40G provides digital image capture for conventional film/screen radiographic examinations.

The device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription Use ✓ OR
(Per 21 CFR 801.109)

Over-The-Counter Use _____

(Optional Format 1-2-96)

David A. Segerson
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023750
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